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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-14-14AQA]

Proposed Data Collections Submitted for
Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. To request more information on the below proposed project or to obtain a copy of the information collection plan and instruments, call 404-639-7570 or send comments to Leroy Richardson, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. Comments are invited on:

(a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility;

(b) the accuracy of the agency's estimate of the burden of the

proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to collected; (d) ways to minimize the burden of the collection of information on respondents, including through the automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. comments should be received within 60 days of this notice.

Proposed Project

The Enhanced STD surveillance Network (eSSuN) — New - Division of STD Prevention (DSTDP), National Center for HIV/AIDS, Viral

Hepatitis, STD, and TB prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Enhanced STD Surveillance Network (eSSuN) project is an active STD sentinel surveillance network comprised of 10 surveillance sites including Baltimore City Health Department, California Department of Public Health, Florida Department of Health, Massachusetts Department of Public Health, Minnesota Department of Health, Multnomah County Health Department, New York City Department of Health & Mental Hygiene, Philadelphia Department of Public Health, San Francisco Department of Public Health, and Washington State Department of Health.

The enhanced STD Surveillance Network is a sentinel surveillance initiative designed to collect longitudinal data of a magnitude sufficient to detect trends and changes over time in the clinical and demographic characteristics of persons presenting for care in STD and family planning/ reproductive health clinical facilities and those being diagnosed and reported with gonorrhea in funded jurisdictions. Data collection activities will be ongoing and continuous and will take five years to complete to establish annual trends, allowing for accretion of a sufficient number of investigated cases or

patient visits to detect statistically meaningful differences between population sub groups.

While routine STD surveillance activities are ongoing in all states and jurisdictions through the National Notifiable Disease Surveillance System, these data do not include the patient populations and specific clinical data elements and behavioral data proposed for collection in eSSuN. No other sources of information currently collected by, or available to, CDC answer the specific questions eSSuN is designed to answer.

A similar data collection infrastructure, the STD Surveillance Network (OMB No. 0920-0842), expires on September 30th, 2015. However, funding for this cooperative agreement ended in September 29th, 2013 and the protocols have been retired. The enhanced STD network is not a continuation of SSuN, instead, it is a new initiative to collect different kinds of data in different jurisdictions and to respond to different national objectives.

The objectives of the eSSuN Project are (1) provide a dataset of supplemental information on case reports of STDs of interest; (2) provide geographic information on case reports of STDs of interest for investigating social determinants of STDs; (3) monitor screening coverage for chlamydial infection among young women in sentinel clinical settings; (4) monitor STD screening, incidence, prevalence, epidemiologic and health care

access trends in populations of interest such as men-who-have-sex-with men (MSM), young people and persons diagnosed with gonorrhea; (5) monitor STD treatment and prevention services practices; (6) monitor selected adverse health outcomes of STDs; (7) evaluate and enhance local and state STD surveillance capacity; (8) enhance local STD-specific health information technology and epidemiologic capacity, and, (9) establish a core of exemplary state, tribal, territorial, county and/or city health department STD surveillance programs employing innovative approaches to STD surveillance.

This project collects data using two surveillance strategies; (1)enhanced surveillance in participating STD and Family planning/reproductive health clinics and (2)enhanced gonorrhea surveillance on a random sample of persons diagnosed with gonorrhea in participating jurisdictions of these 10 local and state health departments.

For the clinic-based surveillance, participating sites have developed common protocols stipulating which data elements would be collected, including demographic, clinical, risk and sexual behaviors. The specified data elements are abstracted from existing electronic medical records for (1) all patient visits to participating STD clinics and (2) for all female patient visits aged 15-44 years of age to participating family planning/reproductive health clinics. Data are de-identified and

recoded by health departments and then are transmitted to CDC through secure file transport mechanisms on an every two month basis. Each eSSuN site will spend 16 hours to transmit the data to CDC every two months. At CDC, data will be aggregated with data from all participating sites in a common language and formatted for analysis.

For the population-based surveillance, a random sample of individuals reported with gonorrhea residing within participating jurisdictions are interviewed using locally designed interview templates.

Enhanced data collection includes detailed information on demographic characteristics, behavioral risk factors and clinical history of persons with gonorrhea. Each of the 10 sites will interview a minimum of 250 persons or 2.5% of total morbidity if annual GC cases exceed 10,000 cases and each interview is expected to take about 10 minutes per person. Data for the population-based component will be collected through telephone-administered or in-person interviews conducted by trained interviewers in the 10 eSSuN sites.

The survey results will be entered into the existing information systems at each health department and sent to CDC through secure file transport mechanisms on an every two month basis.

This information is being collected to (1) enhance and improve STD surveillance data, (2) inform a more comprehensive understanding of tends and determinants of STDs of interest, (3)monitor public health program impact and (4) provide a more robust evidence base for directing public health action in the US.

Participation is voluntary. There is no cost to the respondents other than their time.

Estimate of Annualized Burden

Type of Respondent	Form Name	No. of Respondent s	No. of Responses per Responden t	Average Burden per Response (Hours)	Total Burde n Hours
Data manager at clinic (Electronic transmittal of clinical variables in clinic databases)	Record Abstraction	33	6	3	594
Data manager at each of the 10 local/state health department	Record Abstraction	10	12	16	1920
Gonorrhea cases sampled	Telephone/ in-person interview	3,225	1	10/60	538

Total

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